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Sara K. Ledford

Indiana University School of Law

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The Implications of *Kumho Tire*: Applying Daubert Analysis to Warning-Label Testimony in Products Liability Cases

SARA K. LEDFORD*

INTRODUCTION

The standard governing the admissibility of expert witness testimony has undergone significant changes recently. It has become clear that the old common-law standard, as set out in *Frye v. United States*,¹ has been replaced by a method of analysis centered primarily on the Federal Rules of Evidence ("FRE"). The new standard, as set out by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*² and clarified in *Kumho Tire Co. v. Carmichael*,³ has illuminated the approach to be taken in the evaluation of the admissibility of all expert witness testimony. However, this approach has primarily been developed in scientific and technical expert areas, and many questions still exist regarding the applicability and effectiveness of the standard as applied to social-science expert testimony. The purpose of this Note is to explore the implications associated with applying the new standard to social-science expert witness testimony. To explore these implications, this Note will first set out the roots and development of the new standard. Then, Part II of this Note will set out the development of the factors for evaluating scientific and technical expert witness testimony. Part III will apply the new standard of analysis to an area of social science and illustrate the potential problems that exist under such an analysis. This Note will demonstrate the analysis and accompanying problems by applying the factors to potential testimony by an expert testifying about the effectiveness of warning labels in products liability cases.

I. THE DEVELOPMENT OF THE MODERN EXPERT-WITNESS-TESTIMONY STANDARD

The standard for admitting the testimony of expert witnesses has undergone several changes in the past eighty years. There are four major steps in the chronology of events that have led to the standard currently in force. First, the standard that was used for most of the twentieth century was developed in *Frye* in 1923.⁴ Then the FRE, as adopted in 1975,⁵ set out a new standard for the admissibility of expert

* J.D. Candidate, 2001, Indiana University School of Law—Bloomington; B.A., 1998, University of Michigan—Ann Arbor. I would like to thank my parents, Joel and Karen, and my brother, Tim, for all the support and encouragement they have given me throughout my life. I would also like to thank Professors Donald H. Gjerdingen and Aviva Orenstein for their helpful comments on various drafts of this Note.

1. 293 F. 1013 (D.C. Cir. 1923).

2. 509 U.S. 579 (1993).

3. 526 U.S. 137 (1999).

4. *Frye*, 293 F. at 1014; see KENNETH R. FOSTER & PETER W. HUBER, JUDGING SCIENCE 11 (1997).

5. ERIC D. GREEN ET AL., FEDERAL RULES OF EVIDENCE, at xii (Aspen Law & Bus. 1997).

witness testimony.⁶ The impact of the rules was not fully felt until the third step was taken by the U.S. Supreme Court when it decided *Daubert* in 1993.⁷ The fourth step in this chronology of events is *Daubert*'s progeny. Of the cases following *Daubert*, this Note will focus primarily on *Kumho Tire*. This Part will show the development of each of these steps and attempt to illustrate the impact of each step on the standard for the admissibility of expert witness testimony.

A. *Frye v. United States*

The *Frye* case developed the standard that is the starting point of this Note's analysis. *Frye* involved the use of a systolic blood pressure deception test, a predecessor to the modern lie detector test,⁸ in a criminal case.⁹ Defense counsel wanted to call the scientist who administered the deception test to the defendant as an expert witness at trial.¹⁰ The trial court did not allow it, and the issue was appealed to the Court of Appeals for the District of Columbia.¹¹ In their brief, defense counsel argued that "[w]hen the question involved does not lie within the range of common experience or common knowledge, but requires special experience or special knowledge, then the opinions of witnesses skilled in that particular science, art, or trade to which the question relates are admissible in evidence."¹² Although this may be true as a general principle, the court went a bit further in holding that "while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs."¹³ This is what became known as the *Frye* general acceptance test. Under the *Frye* general acceptance test much deference was given to the judgment of the relevant scientific community, thereby allowing trial judges to avoid many of the difficulties and complexities associated with determining the admissibility of scientific expert evidence.¹⁴ As with most judicially created tests, the general acceptance test was not without problems. One significant problem involved the admissibility of new evidence that had not yet been published.¹⁵ Lack of publication meant that the evidence had not yet had an opportunity to gain acceptance by the relevant scientific community.¹⁶

6. FED. R. EVID. 702-705.

7. See Judge Harvey Brown, *Eight Gates for Expert Witnesses*, 36 HOUS. L. REV. 743, 780 (1999).

8. FOSTER & HUBER, *supra* note 4, at 225.

9. *Frye*, 293 F. at 1013.

10. *Id.* at 1014.

11. *Id.* at 1013-14.

12. *Id.* at 1014.

13. *Id.*

14. Brown, *supra* note 7, at 778-79.

15. ROSEMARY J. ERICKSON & RITA J. SIMON, *THE USE OF SOCIAL SCIENCE DATA IN SUPREME COURT DECISIONS* 23 (1998).

16. *Id.*; Brown, *supra* note 7, at 779.

B. The Federal Rules of Evidence

The next major event in the development of the current expert witness standard was the adoption of the FRE, which were enacted into law in 1975.¹⁷ FRE 702 through 705 govern the use of expert witness testimony. The rule that is of most importance in this analysis of expert witness testimony is Rule 702, as it is the one that has received the majority of the Supreme Court's attention.¹⁸ Rule 702 states: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."¹⁹ Despite the fact that the enacted rules contained provisions governing the admissibility of expert witness testimony, the *Frye* general acceptance test continued to be the primary test used in federal courts.²⁰ The expert witness provisions in the rules did not become significant until the Supreme Court decided *Daubert* in 1993.²¹

C. Daubert v. Merrell Dow Pharmaceuticals, Inc.

The third stage in the development of the current expert-witness-testimony standard was the Supreme Court's decision in *Daubert*.²² In *Daubert*, the parents of two minor children were suing Merrell Dow, the manufacturer of the drug Bendectin.²³ The parents alleged their children's birth defects had been caused by the respective mothers' use of the drug during their pregnancies.²⁴ The defendant moved for summary judgment and submitted an affidavit from an expert in support of its position.²⁵ The expert stated that he conducted an extensive literature review regarding Bendectin and birth defects and that not one of the over thirty studies he reviewed found the drug to cause birth defects.²⁶ The plaintiffs responded to the motion for summary judgment by offering evidence, which purported to show that Bendectin could cause birth defects, from eight of their own experts.²⁷ The various methodologies used by the plaintiffs' eight experts ranged from test tube and live animal studies to pharmacological studies and reanalysis of existing epidemiological studies.²⁸ Although the FRE pertaining to expert witnesses were already in force,²⁹ the district court granted the defendant's motion for summary judgment based on the

17. GREEN ET AL., *supra* note 5, at xii.

18. See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

19. FED. R. EVID. 702.

20. *Daubert*, 509 U.S. at 585; FOSTER & HUBER, *supra* note 4, at 11.

21. Brown, *supra* note 7, at 779-80.

22. *Daubert*, 509 U.S. at 579.

23. *Id.* at 582.

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.* at 583.

28. *Id.*

29. See GREEN ET AL., *supra* note 5, at xii.

Frye general acceptance test.³⁰ According to the district court, scientific evidence was only admissible when it was “‘sufficiently established to have general acceptance in the field to which it belongs.’”³¹ Applying this principle, the district court concluded that any expert opinion that was not based on epidemiological evidence was inadmissible.³²

In affirming the district court’s decision to grant summary judgment for Merrell Dow, the Ninth Circuit Court of Appeals also relied on the *Frye* general acceptance test.³³ The court of appeals stated that scientific evidence was not admissible “unless the technique is ‘generally accepted’ as reliable in the relevant scientific community.”³⁴ The court of appeals took particular issue with the reanalysis of the epidemiological studies.³⁵ The court’s primary concern was that the reanalyses had not been published nor subjected to any other kind of peer review.³⁶ The plaintiffs appealed and the Supreme Court granted certiorari.³⁷

The argument the petitioners presented before the Supreme Court took issue with the validity of the *Frye* general acceptance test.³⁸ The central tenet of their argument was that the *Frye* test had been superseded by the FRE.³⁹ The Court agreed with the petitioners’ argument⁴⁰ and stated “[n]othing in the text of . . . Rule [702] establishes ‘general acceptance’ as an absolute prerequisite to admissibility.”⁴¹ In addition to the fact that the text of the rule does not take into account the *Frye* general acceptance test, the Court also noted that the legislative history was devoid of any reference to that test.⁴² The Court went on to state that “[g]iven the Rules’ permissive backdrop and their inclusion of a specific rule on expert testimony that does not mention ‘general acceptance,’ the assertion that the Rules somehow assimilated *Frye* is unconvincing.”⁴³ Based on this, the Court concluded that the *Frye* general acceptance test should not be the primary test used in federal courts to determine the admissibility of expert testimony.⁴⁴

However, the Court was quick to point out that because that test was no longer the standard did not mean there were no standards to use as guidance in determining the

30. See *Daubert*, 509 U.S. at 583.

31. *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 727 F. Supp. 570, 572 (S.D. Cal. 1989)).

32. *Id.* at 583-84.

33. *Id.* at 584.

34. *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 951 F.2d 1128, 1129 (9th Cir. 1991)).

35. *Id.*

36. *Id.*

37. *Id.* at 585.

38. *Id.* at 587.

39. *Id.*

40. *Id.*

41. *Id.* at 588.

42. *Id.*

43. *Id.* at 589.

44. *Id.* The general acceptance test is no longer the standard used to determine the admissibility of expert witness testimony but is one of the several factors that may be considered under the *Daubert* analysis. See discussion *infra* Part II.D.

admissibility of scientific evidence.⁴⁵ "To the contrary, under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."⁴⁶ The Court based this conclusion primarily on Rule 702 and the two requirements it identified as flowing from that rule.⁴⁷ The first requirement the Court viewed Rule 702 to establish was one of evidentiary reliability.⁴⁸ The Court felt that the phrase "scientific knowledge" indicates both that the evidence has "a grounding in the methods and procedures of science" and "connotes more than subjective belief or unsupported speculation."⁴⁹ The second requirement established by Rule 702 was that of relevance.⁵⁰ "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."⁵¹

Having considered the requirements of Rule 702, the Court established a new standard for the evaluation of expert scientific evidence. Under the new standard, "the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue."⁵² Clearly, this standard involves a two-pronged analysis that the trial judge must undertake.⁵³ First, the judge must determine whether the methodology that serves as the foundation for the testimony is sound.⁵⁴ Then, the trial judge must determine if that methodology can be appropriately applied to the facts of the particular case at hand.⁵⁵

The Court then proceeded to set out several factors that can be useful in performing this two-pronged analysis.⁵⁶ The first factor the Court discussed was whether the particular evidence being offered can be tested.⁵⁷ The primary concern the Court identified here was falsification.⁵⁸ The possibility that evidence could be falsified, even if it has not, is an indication of the reliability of the evidence. The second factor the Court enumerated was "whether the theory or technique has been subjected to peer review and publication."⁵⁹ The Court stated that the idea behind this factor was that by undergoing this process there is a chance that the problems or errors that exist in the methodology will be discovered.⁶⁰ Evidence that has successfully survived this process has another indicator of reliability supporting it. However, the Court made

45. See *Daubert*, 509 U.S. at 589.

46. *Id.*

47. *Id.* at 589-91.

48. *Id.* at 590.

49. *Id.*

50. *Id.* at 591.

51. *Id.* at 591-92.

52. *Id.* at 592.

53. *Id.* at 592-93.

54. *Id.*

55. *Id.* at 593.

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

it clear that this is not an absolute requirement for admissibility.⁶¹ Part of the Court's logic behind this result was that new theories that are scientifically sound may not yet be published, and this lack of publication may not indicate unreliability, but rather newness.⁶²

The third factor that the Court said may be taken into consideration was the error rate and the existence of standards relating to the procedures and operation of any given scientific technique or principle.⁶³ The final factor the Court gave was the general acceptance of the principle or technique.⁶⁴ The Court envisioned the role of the general acceptance test as follows: "A 'reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community.'"⁶⁵

The Court was careful to stress that this Rule 702 inquiry is flexible with the focus on relevance and reliability as indicators of scientific validity.⁶⁶ The Court also emphasized the fact that this analysis focuses only on the manner in which the evidentiary conclusions are generated, not on the conclusions themselves.⁶⁷ In essence, the Court held that general acceptance is not an absolute requirement for the admissibility of scientific evidence, but the trial judge now has the responsibility to ensure that the expert scientific evidence is reliable and relevant to the case at bar.⁶⁸ The Ninth Circuit, on remand, added one more factor to this basic list of factors.⁶⁹ This factor asks whether the research was conducted independent of the litigation or was prepared solely for the purposes of testifying in a particular case.⁷⁰

The Court's opinion in *Daubert* only discusses scientific expert evidence.⁷¹ However, in addition to scientific knowledge, Rule 702 includes technical and other specialized knowledge.⁷² This apparent inconsistency led many to question whether the *Daubert* analysis applied to experts other than scientific experts. This dilemma was resolved in the *Kumho Tire* decision.⁷³

D. *Kumho Tire Co. v. Carmichael*

In *Kumho Tire*, the Court considered "how *Daubert* applies to the testimony of engineers and other experts who are not scientists."⁷⁴ The case arose out of an accident that occurred when a tire on the respondents' minivan blew out and caused

61. *Id.* at 594.

62. *Id.* at 593.

63. *Id.* at 594.

64. *Id.*

65. *Id.* (quoting *United States v. Downing*, 753 F.2d 1224, 1238 (3d Cir. 1985)).

66. *Id.*

67. *Id.* at 595.

68. *Id.* at 597.

69. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311 (9th Cir. 1995).

70. *Id.* at 1317.

71. *Daubert*, 509 U.S. at 590 n.8.

72. FED. R. EVID. 702.

73. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

74. *Id.* at 141.

an accident killing one passenger and injuring several others.⁷⁵ The respondents brought suit alleging that the tire, manufactured and distributed by the petitioners, was defective.⁷⁶ The main support for the respondents' case was based heavily on the testimony of a tire-failure-analysis expert.⁷⁷

The Court was called upon to decide if the *Daubert* analysis applied to the tire-failure expert's testimony.⁷⁸ In arriving at the conclusion that the *Daubert* analysis applies to all expert witness testimony,⁷⁹ the Court used the following logic. First, the language of Rule 702 "makes no relevant distinction between 'scientific' knowledge and 'technical' or 'other specialized' knowledge. It makes clear that any such knowledge might become the subject of expert testimony."⁸⁰ The Court then pointed out that the word "knowledge" establishes the notion of reliability in *Daubert*, not the word "scientific."⁸¹ Thus, the reliability requirement carries over to technical knowledge and other specialized knowledge. It further clarified the point that the reason the *Daubert* opinion only refers to scientific expert testimony is because that was the type of expert testimony at issue in that case.⁸² The Court then pointed out that there is no clear division between scientific expert evidence and technical or otherwise specialized expert evidence, so it would be exceedingly difficult for judges to apply the expert witness rules if they had to make such a distinction prior to the application of the FRE.⁸³ For these reasons, the Court concluded that the *Daubert* analysis applies to all types of potential expert witness testimony.⁸⁴

The Court then turned to the application of the *Daubert* analysis to engineering-type evidence. The Court found that the four factors mentioned in *Daubert* may be useful in determining whether the evidence is admissible.⁸⁵ This serves to reinforce the notion that the *Daubert* analysis is flexible in nature and that judges should adapt their analysis to the particular type of expert testimony offered in any particular case.⁸⁶ As the Court noted, the reliability of an expert's testimony may depend on a solid scientific foundation in some situations but may depend on personal knowledge or experience in other situations.⁸⁷ Given the wide range of potential topics of expert witness testimony, it was impossible for the Court to enumerate a completely definitive set of factors that should be considered when determining the admissibility of expert witness testimony.⁸⁸ The key "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an

75. *Id.* at 142.

76. *Id.*

77. *Id.*

78. *Id.* at 146.

79. *Id.* at 147.

80. *Id.*

81. *Id.*

82. *Id.* at 147-48.

83. *Id.* at 148.

84. *Id.* at 149.

85. *Id.* at 150.

86. *See id.*

87. *Id.*

88. *Id.*

expert in the relevant field.”⁸⁹

Following this logic, the Court concluded that the district court had properly conducted a Rule 702 analysis.⁹⁰ The expert had testified that “in the absence of evidence of abuse, a defect will normally have caused a tire’s separation.”⁹¹ He went on to contend that if there were fewer than two of the four total signs of abuse, then the tire was defective.⁹² This, in and of itself, was not the problem. However, when coupled with uncertainties about the effectiveness of the expert’s method of inspection and certain inconsistencies in the expert’s conclusions regarding the degree of abuse necessary to conclude that something other than the defect had caused the problem, the Court decided that the expert’s testimony was properly excluded.⁹³

Although the *Kumho Tire* decision has resolved the issue regarding whether the *Daubert* analysis applies to all expert testimony, some questions remain. One issue is the development of factors judges will use in evaluating the various types of expert evidence. A second issue is how these factors, which to this point have primarily been developed in conjunction with scientific and technical expert testimony,⁹⁴ apply to social-science-type expert evidence. The remaining parts of this Note discuss these two issues.

II. DEVELOPMENT OF THE *DAUBERT*-TYPE FACTORS

In its opinion in the *Daubert* case, the Supreme Court enumerated four factors that may be used to evaluate whether scientific expert witness testimony is reliable and relevant and therefore admissible.⁹⁵ As mentioned earlier, these factors are the ability to be tested or falsified, peer review and publication, error rate and standards, and general acceptance of the principle or technique.⁹⁶ The Ninth Circuit Court of Appeals, when deciding the case on remand,⁹⁷ added a fifth factor to this list. The factor added by the court of appeals takes into consideration whether the expert’s opinion was developed independently of the litigation or strictly with the intent to testify as an expert.⁹⁸ This Part seeks to set out a more in-depth explanation of the development and application of these five primary factors than has been described above. A more detailed understanding of these factors is required before setting up the application of these factors to the hypothetical situation of a warning-label expert witness’s testimony later in this Note.

89. *Id.* at 152.

90. *Id.* at 153.

91. *Id.* at 154.

92. *Id.*

93. *Id.* at 154-56.

94. The *Daubert* case involved medical testimony and other types of hard-science testimony, see *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and the *Kumho Tire* case involved engineering-type testimony, see *Kumho Tire*, 526 U.S. at 140.

95. See *Daubert*, 509 U.S. at 579.

96. See *supra* text accompanying notes 52-60.

97. See *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311 (9th Cir. 1995).

98. *Id.* at 1317.

A. Testing and Falsification

The first factor the Supreme Court discussed in *Daubert* was whether the scientific theory or technique can be tested.⁹⁹ The primary concern of this factor is whether the purported scientific theory is falsifiable.¹⁰⁰ The Court then cited several authorities on the nature of science that supported the notion that the ability to test a hypothesis or theory is one of the features that uniquely identifies scientific principles.¹⁰¹ Essentially, "a statement or theory is . . . falsifiable if and only if there exists at least one potential falsifier—at least one possible basic statement that conflicts with it logically."¹⁰² The logic behind this factor is that although a particular hypothesis may not ever be proven true to a certainty, the hypothesis is more reliable the more often it is tested and is able to weather the storm.¹⁰³

If this logic is followed, one arrives at the conclusion that scientific endeavors should be designed with the goal of falsifying hypotheses or theories as opposed to proving them.¹⁰⁴ Underlying this conclusion is the notion that scientific results that are at odds with established or accepted principles are more useful.¹⁰⁵ This type of result provides new information, as opposed to a scientific experiment with results that just confirm a previously accepted theory.¹⁰⁶ This line of reasoning appears to be at odds with the Court's desired result—evidentiary reliability—because it places more value on the contradictory results. However, the underlying principle does support the Court's intended result. The reliability of a scientific theory or conclusion that is being offered into evidence by an expert is greater if that theory has been subjected to testing and has withstood the attack. This is not to say that the theory is reliable eternally. As new scientific discoveries are made, a new line of attack may eventually find weaknesses in the theory, but at that moment in time, the testing record provides the trial judge with one mechanism for measuring the reliability of the proffered evidence.

Despite the advantages in terms of evidentiary reliability, investigating all the various studies and tests that have attempted to falsify a particular theory could prove

99. *Daubert*, 509 U.S. at 593.

100. *Id.*

101. *Id.* The quotes the Court used are as follows: "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." *Id.* (quoting ERIC D. GREEN & CHARLES R. NESSON, PROBLEMS, CASES, AND MATERIALS ON EVIDENCE 645 (1983)). "[T]he statements constituting a scientific explanation must be capable of empirical test." *Id.* (quoting CARL G. HEMPEL, PHILOSOPHY OF NATURAL SCIENCE 49 (1966)). "[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability." *Id.* (quoting KARL R. POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 37 (5th ed. 1989)).

102. 1999 WILEY EXPERT WITNESS UPDATE 77 (Eric Pierson ed., Aspen Law & Bus. 1999) (quoting Karl R. Popper, *Realism, and the Aim of Science*, in THE POSTSCRIPT TO THE LOGIC OF SCIENTIFIC DISCOVERY (W. Bartley III ed., 1983)).

103. FOSTER & HUBER, *supra* note 4, at 38.

104. *Id.* at 42.

105. *Id.*

106. *Id.* at 42, 44.

to be an arduous task for a trial judge. One way to begin this potentially daunting task is for the trial judge to examine the null hypothesis.¹⁰⁷ This is a way to ensure that the expert positing the theory took at least the minimum attempt to falsify his or her hypothesis.¹⁰⁸ The contention that there is a significant difference between the treated and the untreated control group can be understood as falsification of the opposite of the originally proposed theory.¹⁰⁹

B. Error Rate

Another factor discussed by the Supreme Court in *Daubert* was the rate of error.¹¹⁰ The Supreme Court, in *Daubert*, includes in its description of this factor both the consideration of the rate of error and the existence of standards that regulate or control the operation of a particular scientific mechanism.¹¹¹ The application of this factor to determine the admissibility of expert testimony involves several different issues for the trial judge to examine. First, there are multiple types of errors that can, and do, occur during scientific research.¹¹² The trial judge must be prepared to assess the effect of all these different types of errors.¹¹³ The next thing the judge must consider is the existence of standards that govern particular experimental processes and mechanisms and the nature of the enforcement of those very standards, if they exist.¹¹⁴

The multitude of errors that can occur in a scientific research endeavor can, and do, occur throughout every stage of the research process for a variety of reasons.¹¹⁵ One type of error that occurs is random error.¹¹⁶ This is generally the least problematic type of error to consider for scientists and judges alike, because this type of error tends to balance out over the course of many repetitions of an experiment or procedure.¹¹⁷ As long as a sufficient number of trials or repetitions are undertaken, this type of error should not affect the reliability of the results. In most situations, this would seem to be a relatively simple inquiry for a trial judge to make regarding the reliability of the particular scientific evidence at issue.

A more troublesome type of error is systematic error.¹¹⁸ Systematic errors may include problems with the parameters or boundaries of the experiment such that the mechanism consistently over-reports false instances or under-reports true instances

107. See *id.* at 49. The null hypothesis is "the assertion that the treated and untreated groups in an experiment do not differ significantly with respect to some characteristic under scrutiny." *Id.*

108. *Id.*

109. *Id.*

110. See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993).

111. See *id.*

112. See FOSTER & HUBER, *supra* note 4, at 72.

113. See *id.* at 70.

114. See, e.g., *id.* at 100-01 (discussing use of good laboratory and clinical practices to ensure integrity of scientific data).

115. See *id.* at 70, 72.

116. *Id.* at 70.

117. *Id.*

118. *Id.* Systematic errors are defined as those that "are the same for every measurement, or are a function of the value of the quantity being observed." *Id.*

of the variable being measured,¹¹⁹ sampling error,¹²⁰ or data manipulation.¹²¹ These types of errors can be more difficult to detect. If the problem lies in the design of the mechanism or experiment, it may be particularly hard for a trial judge to detect this type of systematic error, especially if the procedures involved are highly specialized and technical. It may also be difficult to detect certain types of data manipulation.¹²² For example, a judge or even another scientist can examine the reported results of any given experiment but cannot know what, if anything, was excluded from the report.¹²³

Data manipulation may be of particular concern in the area of expert witness testimony because of the pressures that are brought to bear on the expert witness due to the advocate's role in the American legal system.¹²⁴ There is one tool that can be utilized in assessing this area of error—the existence of standards governing the technique or the field of science in general.¹²⁵ If such standards exist, an evaluation of the reliability of the results of the scientific inquiry can be made based on whether the expert complied with those standards. Another relatively easy indicator for the trial judge to determine is whether the particular expert has considered and evaluated the potential sources of error in the scientific results and conclusions that are being offered as testimony.¹²⁶ “A scientist's failure or unwillingness to directly confront potential errors in his or her own work is almost conclusive proof, in and of itself, that the work is flawed.”¹²⁷

C. Peer Review and Publication

A third factor the trial judge considers when determining the reliability of the potential expert witness testimony is whether the basis of the testimony offered by the expert “has been subject to peer review and has been published.”¹²⁸ The logic behind the Supreme Court's inclusion of this factor is that peer review increases the probability that problems or errors that may be present in the research process or the ultimate results will be discovered.¹²⁹ The Court is quick to point out, however, that publication (which it views as an element of the peer-review process)¹³⁰ is not an absolute requirement for the admissibility of evidence, because this may exclude scientifically solid theories that are too new to have made it through the publication process yet.¹³¹ In some ways this factor is connected to whether a theory or proposition being offered by the expert can be tested. While peer review does not and cannot prove to a certainty that the theory is true, it does provide a record of the

119. *Id.* at 76.

120. *Id.*

121. *See id.* at 95-96.

122. *Id.* at 96, 100.

123. *Id.* at 100.

124. *Id.* at 101-02.

125. *Id.* at 100-01.

126. *See id.* at 83.

127. *Id.*

128. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993).

129. *Id.*

130. *Id.* at 593-94.

131. *Id.* at 593.

instances in which the theory has been tested.¹³² What the peer-review system does provide is a method of "ensur[ing] a threshold level of reliability for published scientific reports."¹³³ This level of reliability flows from the fact that the theory has been tested and has subsequently passed the test.¹³⁴

While this minimum level of reliability is relatively easy for a trial judge to gauge, there are some problems within the system that are not as easily ascertainable. This process is a good mechanism for eliminating the scientific papers that are seriously flawed or clearly erroneous, but it can be easy for a reviewer to miss the subtler, less obvious problems.¹³⁵ There are several reasons for this. First, the reviewers often do not have the opportunity to see the original data—they are confined to reviewing only what was submitted.¹³⁶ This not only prevents the reviewer from seeing what data was left out regarding data manipulation, but also keeps him or her from double-checking the calculations and statistical analysis.¹³⁷ Another factor contributing to the inability to detect less than obvious problems is that the multiplicity of scientific journals in existence allows the author of a paper to cruise the journal circuit, making slight modifications and perhaps covering up problems, until the article is accepted by a journal.¹³⁸

The problems with the peer-review system emphasize the fact that, while a survey of peer-reviewed publications regarding a particular theory or proposition is relatively easy for a trial judge to do, it is important to remember that in most scientific debates it will most likely be possible to find a few peer-reviewed articles that support the underdog theory.¹³⁹ For this reason and the fact that new or very narrow theories may not have been published yet, it is important that the judge not place a disproportionate amount of emphasis on the peer-review factor.

D. General Acceptance Test

As the fourth enumerated factor in *Daubert*, the Supreme Court stated that the *Frye* general acceptance test could yet be of some use.¹⁴⁰ "Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community,' may properly be viewed with skepticism."¹⁴¹ However, the Court was quick to qualify this statement by stating that an exacting analysis of this sort is not required when determining the reliability of evidence.¹⁴²

Given the continued, yet somewhat less prominent, viability of the general acceptance test, a more in-depth discussion of this factor is necessary. The test

132. FOSTER & HUBER, *supra* note 4, at 163.

133. *Id.* at 180.

134. *Id.* at 163.

135. *Id.* at 171.

136. *Id.* at 171, 174.

137. *Id.* at 174.

138. *Id.* at 175.

139. *See id.* at 175 (citation omitted).

140. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594 (1993).

141. *Id.* (quoting *United States v. Downing*, 753 F.2d 1224, 1238 (3d Cir. 1985)).

142. *Id.*

consists of a two-pronged analysis.¹⁴³ First, the relevant scientific community must be identified.¹⁴⁴ Then, the level of acceptance within that community of the methodology in question must be assessed.¹⁴⁵ This test does have its problems, though, which have led some to the conclusion that it is unreliable.¹⁴⁶ The primary concern is that as the relevant scientific community becomes increasingly specific, more and more evidence will be excluded until only the most widely accepted, mainstream theories remain.¹⁴⁷ It seems a fair assumption to conclude that the Supreme Court recognized this in *Daubert* and thus made it one of several potentially relevant factors for determining reliability, rather than the exclusive test. By requiring that the analysis include multiple factors that a trial judge can balance, the tendency of the general acceptance test to exclude new and unique scientific evidence can be offset, provided that the new evidence's reliability is demonstrated in some other manner.

E. Independence of Research from the Litigation

The fifth primary factor of the *Daubert* analysis was not actually identified by the Supreme Court but was implemented by the Ninth Circuit in deciding the case on remand.¹⁴⁸ As the Ninth Circuit put it, "One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying."¹⁴⁹ In a way, this ties into the earlier discussion about data manipulation. Findings based on research that was conducted independently of the litigation at hand provide an indication of reliability in that the expert will not have as much room or motivation to manipulate the data to support the position of the client.¹⁵⁰

On a related note, conducting the research before there is the possibility of testifying as an expert witness will reduce the possibility that the expert will, consciously or unconsciously, bias the results of the research in favor of the result expected by the client and the attorney.¹⁵¹ The independent nature of the research also limits the attorney's ability to "shop" for an expert that will support her theory of the case. There will be a finite number of experts that are doing research in the particular field in question, and only a limited number of which, if any, will support the position taken by the attorney no matter whether she is representing the plaintiff or defendant.¹⁵² This logic led Judge Kozinski, in writing for the Ninth Circuit, to conclude that this factor is the most critical in determining that the proffered scientific

143. Barbara Frederick, *Daubert v. Merrell Dow Pharmaceuticals, Inc.: Method or Madness?*, 27 CONN. L. REV. 237, 251 (1994).

144. *Id.*

145. *Id.*

146. *Id.*

147. *Id.*

148. See *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.*

evidence is good, reliable science and not junk science.¹⁵³

III. WARNING LABELS AS AN EXAMPLE OF SOCIAL-SCIENCE TESTIMONY

In keeping with the spirit of the *Kumho Tire* decision, which extended the application of the *Daubert* analysis to all expert witness testimony, this Part applies that analysis to an area of social-science expert testimony. The first section of this Part will apply the five primary *Daubert* factors discussed above to the hypothetical testimony of an expert witness testifying in a products liability case regarding the duty to warn and, more specifically, about the effectiveness of warning labels. The second section of this Part will analyze any problems that arise in the application of the five primary factors to the warning-label expert's testimony and propose new factors that may be more useful to determine the admissibility of a social-science expert's testimony, specifically the hypothetical warning-label expert, in the flexible analysis envisioned by *Daubert* and its progeny. Before either of these steps can be taken, a brief discussion of modern products liability law and the role of warning labels is in order to better understand the nature of expert testimony in this area and the role it plays.

A. Products Liability and Warning Labels

The primary logic behind the law of products liability is to compensate for the losses caused by defective products.¹⁵⁴ The basic tenet stated by the *Restatement (Third) of Torts: Products Liability* is: "One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect."¹⁵⁵ The next logical question is: What is a defective product? The *Restatement* defines several categories of defective products.¹⁵⁶ For the purposes of this Note, only one category, as defined by the *Restatement*, is important and is defined as follows:

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

. . . .
(C) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.¹⁵⁷

The logic behind classifying inadequate instructions or warnings as a product defect

153. *Id.* at 1317-18.

154. ALVIN S. WEINSTEIN ET AL., PRODUCTS LIABILITY AND THE REASONABLY SAFE PRODUCT 4 (1978).

155. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1997).

156. *See id.* § 2.

157. *Id.*

is that "the danger level of the product can be substantially reduced by carefully worded warnings and instructions on product use and the possible consequences of misuse."¹⁵⁸ This Note does not purport to be a detailed analysis of the interaction between the duty to warn and warning labels on products. For the purposes of this Note, it is sufficient to state that the adequacy and effectiveness, or reasonableness, of the warnings is one factor that may be at issue in a products liability case and therefore may be the subject of expert witness testimony.¹⁵⁹

Generally, to be considered adequate, a warning label must fulfill the following functions (or some combination thereof):¹⁶⁰ identify the hazard and potential injury, identify the intensity of the hazard, supply information that illustrates how to avoid the hazard, and clearly communicate these factors.¹⁶¹ There are a number of factors that play a part in determining if a warning label is adequate. Some general categories of factors that play a role in determining the adequacy of a warning label include: the intensity of the warning,¹⁶² the placement of the warning on the product,¹⁶³ the use of pictures or symbols,¹⁶⁴ the selection of a signal word,¹⁶⁵ the color,¹⁶⁶ and the clarity of the language used in the warning.¹⁶⁷ Accordingly, this broad range of factors provides a wide range of potential topics for expert testimony. Based on the intended functions of a warning label and the factors that are involved in determining if those functions have been adequately served, it is possible to see that there is a certain subjectivity

158. WEINSTEIN ET AL., *supra* note 154, at 40.

159. Note, however, that even if a warning label is adequate it may not relieve the manufacturer or distributor of liability if a relatively simple design change could have decreased or eliminated the likelihood of harm. Alvin S. Weinstein, *Consensus Standards for Warning Labels: Prescriptive but Not Protective*, in *PRODUCT LIABILITY WARNINGS, INSTRUCTIONS, AND RECALLS* 1984, at 153, 156-57 (1984) [hereinafter *PRODUCT LIABILITY WARNINGS*].

160. Kenneth Ross, *Creating the Warning Label System and Meeting the Duty to Instruct*, in *PRODUCT LIABILITY WARNINGS*, *supra* note 159, at 119, 121; Weinstein, *supra* note 159, at 160. As would be expected, there is not complete consensus on the elements or functions of an adequate warning label.

161. Ross, *supra* note 160, at 121; Weinstein, *supra* note 159, at 160.

162. Barbara Wrubel, *Liability for Failure to Warn or Instruct*, in *PRODUCT LIABILITY WARNINGS*, *supra* note 159, at 9, 40 ("[A] warning may be deemed inadequate if it is not sufficiently intense; that is, if the language of the warning is not commensurate with the gravity of the harm likely to result from the danger." (citing *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973))); *see also* Ross, *supra* note 160, at 121.

163. Wrubel, *supra* note 162, at 42; *see also* Ross, *supra* note 160, at 121.

164. Ross, *supra* note 160, at 121.

165. Weinstein, *supra* note 159, at 162. There are three general classifications of signal words that roughly correlate to the intensity of the harm. In order from most intense to least, the generally recognized signal words are danger, warning, and caution. *Id.*; *see also* Ross, *supra* note 160, at 125.

166. Ross, *supra* note 160, at 125. There is also a continuum of color correlated to the intensity of warning, with the most intense being red, which is followed by orange, and finally yellow. *Id.*

167. *Id.* at 121. The factors mentioned above will be explained in further detail as they are used in the following hypothetical reliability analysis of a warning-label expert's testimony.

involved in the creation and evaluation of warning labels.¹⁶⁸ Most likely, this subjectivity will be reflected in any testimony offered by expert witnesses regarding warning labels and may create difficulties in applying the *Daubert* reliability analysis to expert testimony. Testimony regarding warning labels would clearly not be classified as being based on a hard science or technical field. The most likely discipline for this type of testimony to be based on is psychology, as it involves attracting users' attention to the label and then getting them to comprehend the danger that is being warned against.

B. Applying the Five Primary Daubert Factors to Warning Labels

Having briefly set out relevant considerations, the focus of this Note now shifts to applying the five primary *Daubert* factors to warning-label expert witness testimony. The first of these is whether the theory can be tested or falsified. The analysis under this factor will be highly dependent upon the methodology used by the expert in conducting his or her research. The most likely methodology used by a warning-label expert would involve creating several warning labels that varied with respect only to a single characteristic and then gauging peoples' reactions to the various labels.

For example, one could gauge the reactions of groups of people to a "red danger" label as opposed to an "orange danger" label.¹⁶⁹ Then, if more people paid attention to the red label, but the defendant in a product liability case had used an orange label, the expert could then testify about the likelihood of preventing the accident if a red label had been used instead. One indicator the trial judge could use to assess the reliability of the offered testimony is the null hypothesis. In the red-orange color example, evaluating a "danger" label that did not use any color, but was only black and white would test the null hypothesis. As stated earlier, this would be an indication as to whether the expert attempted to falsify his or her own theory. In this regard, the use of this indicator does not vary significantly from the evaluation of hard-science evidence to the evaluation of social-science evidence. Also, as with scientific evidence, the trial judge will be able to assess whether anyone has tested the theory.

Whether anyone else has tested the theory is, of course, related to the second *Daubert* factor, peer review and publication. Clearly, if the results have not been published it is unlikely, though not impossible, that anyone else would have tested the theory. The problem posed by this factor is where does the trial judge look for publications. Obviously, social-science journals and publications do exist. However, it seems highly unlikely that psychology journals would publish any significant number of studies on the effectiveness of warning labels; such studies only being of use to manufacturers who probably do not read psychology journals. Taking this into consideration, the next logical place to look for published studies on warning labels would be trade and industry publications. However, it may then become necessary to take into consideration the source of the publication. Surely, the studies that are

168. Weinstein, *supra* note 159, at 161.

169. The term "red danger" label refers to a warning label with the signal word "danger" that has a red background behind the word. Similarly, an "orange danger" label would have an orange background behind the signal word.

published in trade and industry publications are biased somewhat in favor of the audience that they serve—the industries—and may not receive the same critical type of peer review prior to publication that occurs in more academically oriented journals. This may not be all bad, though, because surely the industries themselves are interested in using adequate warning labels so as to limit their potential liability. However, it does add another degree of uncertainty regarding expert testimony that is being evaluated based on these publications. Thus, peer review might not be a good factor to consider in the determination of the admissibility of expert witness testimony regarding types of testimony that tend not to be published in academic journals.

Accepting the assumption that the most likely place for a study on warning labels to be published is a trade or industry publication leads potentially to another problem. This problem is that persons within the specific field probably publish most of these studies. It seems that within a particular field, those most likely to write an article on warning labels would be those whose jobs bring them into contact with warning labels. This would most likely be the person who develops the warning labels or heads the department that is charged with such development, if one exists. The implication of these facts is that the only people writing these articles are likely to be the very people that would serve as expert witnesses for the manufacturers of the allegedly defective product. Although this concern does not necessarily speak to the reliability of the testimony offered by a particular defendant's expert, it does bring up the question as to whether a plaintiff will be able to find a warning-label expert whose testimony will be reliable enough to be admissible under the *Daubert* analysis.

The utility of the third *Daubert* factor, error rate and standards, could also be affected by the fact that most of the people involved in the study of warning labels are associated with the industry that produces the products that need such warnings. This association gives rise to a possible motive for the manipulation of data. Since the potential authors of these studies know the preferences of their target audience this may have an impact, even unintentionally, on the results they derive from the research.

There is potential for data manipulation and error in a more general manner also. Psychological and other social-science research studies often require the active, cognizant participation of human beings, unlike many science experiments that are strictly laboratory-based studies of physical elements or even medical research that involves determining whether someone has a disease or gene.¹⁷⁰ Much more often in the social-science realm, the researcher must deal with and account for the thought processes of the human subjects he or she is studying. Careless phrasing of questions, for example, can inadvertently introduce an element of error into the information gathered by the researcher.¹⁷¹

Assume, for example, that a researcher is giving a survey about the effectiveness of particular warning labels. The survey first asks a series of questions about colors and symbols used on particular labels and then asks about the intensity of danger associated with a label that uses red as a background color and a large lightning bolt as a symbol. If not composed carefully, the first series of questions may alert, even if only subconsciously, the research subjects as to the answer the researcher is looking

170. See BERNARD PHILLIPS, *SOCIOLOGICAL RESEARCH METHODS* 13 (1985).

171. See CURT R. BARTOL & ANNE M. BARTOL, *PSYCHOLOGY AND LAW* 7 (2d ed. 1994).

for regarding the final question.¹⁷² This would introduce an element of error into the study that may not be easily detectable by the trial judge seeking to determine the reliability of the theory based on this research. This type of error will not show up in the statistical calculation.

Part of the potential data manipulation and error effect is controlled by the existence of standards. Two types of standards are important here. First, just as there is with scientific research, there are certain guidelines social-science researchers are to follow when conducting their experiments. In a reliability analysis, these standards operate in the exact same way that the scientific procedural standards do. The trial judge will discern whether the relevant standards and procedures were followed, and if they were not, then the judge knows to be skeptical of the reliability of the theory being proffered as evidence (or at least the judge knows to look for other factors that indicate reliability under the *Daubert* standard).

The second set of standards that play a role are the standards established for warning labels themselves by the various industry associations. Although merely complying with the minimum standards may not be enough to allow the manufacturer to avoid liability, the standards do provide the judge with one way of assessing the reliability of an expert's proffered testimony by providing a measuring stick to compare against the expert's testimony. If an expert is attempting to argue that a warning label that is far below industry standards was in fact adequate, his testimony may not necessarily be unreliable, but it would be an indication to the judge to at least look for other factors indicating the reliability of the evidence. When it is looked at in this manner, this set of standards can actually be seen as an indication of the general acceptance of the methodology, which was the Supreme Court's fourth factor in the analysis.

The fifth factor, whether the research has been conducted independent of the litigation, creates some problems in the context of warning labels. The primary concern is related to the fact discussed earlier that the only people likely to be publishing on the subject of warning labels are those within a particular industry that regularly work with warning labels. In addition to presenting several concerns in the context of peer review and publication, this scenario also presents some concerns in the context of independence from the litigation. One point to consider is whether the experts that are likely to testify are those that work with the development and implementation of warning labels in a particular industry; if that is the case, the question is whether the research on which they base their testimony can ever be viewed as independent of the litigation. Although the experts would not have done any of their research with the intent of testifying in a particular case, the essence of their work is to prepare warning labels in such a manner that they will be deemed adequate in any particular lawsuit that may arise. Therefore, courts must consider whether it is enough to guarantee reliability by showing that the research was not done in preparation for any particular lawsuit or whether the testimony offered by such experts will be deemed inadmissible because of the general context in which it was developed.

172. PHILLIPS, *supra* note 170, at 234 ("[I]t is important to understand that initial questions convey to the respondent information which he uses to assess the purposes of the study.").

CONCLUSION

Although the warning-label quagmire discussed above is a hypothetical scenario it demonstrates the difficulties a trial judge may face in applying a *Daubert* analysis to any academic discipline that shares similar characteristics. The mere possibility that this situation may rear its ugly head illustrates that the *Daubert* analysis is yet another drain on the increasingly limited resources of the judiciary because it requires judges to engage in an ever-changing analysis of expert testimony.

That is not to say that the *Daubert* standard does not have its benefits; it clearly does. The flexibility it allows in determining reliability, and ultimately admissibility, is critical. As expert testimony becomes more and more commonplace in even the most basic kinds of litigation and the range of topics that are the basis of such expert testimony continues to expand, the possibility of fairly evaluating each and every type of expert testimony with a single, static test becomes more and more unrealistic.

Although this flexibility is the *Daubert* approach's largest benefit, it is also its biggest drawback. As the variety of types of experts called upon to testify increases, the job of the trial judge will become increasingly difficult. The trial judge will have to be able to evaluate more and more types of research methodologies. If the judge is called upon to do this alone in each and every case, the already time-consuming process of a trial, whether civil or criminal, will get even longer.

Most would agree that elongating this already drawn out process is not in the best interest of the judicial system, from both the bench's perspective and the litigant's perspective. It puts a further drain on already limited judicial resources, as well as impeding the speedy resolution of litigants' claims. The dilemma this creates is how to retain the flexibility needed to fairly evaluate a wide array of expert witness testimony while not overly burdening the judicial system.

The best compromise seems to be the use of an independent panel of experts to evaluate proffered testimony and report their conclusions to the trial judge. This panel could operate in a manner similar to that of judicial clerks, except that at least for the time being, one panel should be able to serve a group of judges rather than an individual judge. The panel could also be composed of several experts with varying backgrounds and areas of expertise. For example, there could be a social scientist, an engineer, and a medical doctor. Thus, one of the expert advisors would have at least a minimum degree of familiarity with any given type of expert testimony and accordingly should be able to perform a reliability analysis using the *Daubert* factors more quickly than a judge who would have to start from scratch. This method would allow the individual type of analysis necessary to accurately determine the reliability of a wide range of topics of expert testimony, while also minimizing the effort the judge must exert and keeping any delay attributable to the process as minimal as possible.

